

§ 704.3

40 CFR Ch. I (7–1–11 Edition)

§ 704.3 Definitions.

All definitions as set forth in section 3 of TSCA apply in this part. In addition, the following definitions are provided for the purposes of this part.

Annual means the corporate fiscal year.

Article means a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.

Byproduct means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s).

CAS Number means Chemical Abstracts Service Registry Number.

Coproduct means a chemical substance produced for a commercial purpose during the manufacture, processing, use, or disposal of another chemical substance or mixture.

Customer means any person to whom a manufacturer, importer, or processor directly distributes any quantity of a chemical substance, mixture, mixture containing the substance or mixture, or article containing the substance or mixture, whether or not a sale is involved.

Domestic means within the geographical boundaries of the 50 United States, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

Enclosed process means a manufacturing or processing operation that is designed and operated so that there is no intentional release into the environment of any substance present in the operation. An operation with fugitive,

inadvertent, or emergency pressure relief releases remains an enclosed process so long as measures are taken to prevent worker exposure to and environmental contamination from the releases.

EPA means the United States Environmental Protection Agency.

Import means to import for commercial purposes.

Import for commercial purposes means to import with the purpose of obtaining an immediate or eventual commercial advantage for the importer, and includes the importation of any amount of a chemical substance or mixture. If a chemical substance or mixture containing impurities is imported for commercial purposes, then those impurities also are imported for commercial purposes.

Import in bulk form means to import a chemical substance (other than as part of a mixture or article) in any quantity, in cans, bottles, drums, barrels, packages, tanks, bags, or other containers, if the chemical substance is intended to be removed from the container and the substance has an end use or commercial purpose separate from the container.

Importer means (1) any person who imports any chemical substance or any chemical substance as part of a mixture or article into the customs territory of the United States, and includes:

(i) The person primarily liable for the payment of any duties on the merchandise, or

(ii) An authorized agent acting on his behalf (as defined in 19 CFR 1.11).

(2) Importer also includes, as appropriate:

(i) The consignee.

(ii) The importer of record.

(iii) The actual owner if an actual owner's declaration and superseding bond have been filed in accordance with 19 CFR 141.20.

(iv) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 CFR part 144.

(3) For the purposes of this definition, the customs territory of the United States consists of the 50 States, Puerto Rico, and the District of Columbia.

Environmental Protection Agency

§ 704.3

Impurity means a chemical substance which is unintentionally present with another chemical substance.

Intermediate means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures, or that is intentionally present for the purpose of altering the rates of such chemical reactions.

Known to or reasonably ascertainable by means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.

Manufacture means to manufacture for commercial purposes.

Manufacture for commercial purposes means: (1) To import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes among other things, such "manufacture" of any amount of a chemical substance or mixture:

(i) For commercial distribution, including for test marketing.

(ii) For use by the manufacturer, including use for product research and development, or as an intermediate.

(2) Manufacture for commercial purposes also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Such byproducts and impurities may, or may not, in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical product for a commercial purpose.

Manufacturer means a person who imports, produces, or manufactures a chemical substance. A person who extracts a component chemical substance from a previously existing chemical substance or a complex combination of substances is a manufacturer of that component chemical substance.

Non-isolated intermediate means any intermediate that is not intentionally removed from the equipment in which

it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture. Mechanical or gravity transfer through a closed system is not considered to be intentional removal, but storage or transfer to shipping containers "isolates" the substance by removing it from process equipment in which it is manufactured.

Own or control means ownership of 50 percent or more of a company's voting stock or other equity rights, or the power to control the management and policies of that company. A company may own or control one or more sites. A company may be owned or controlled by a foreign or domestic parent company.

Parent company is a company that owns or controls another company.

Person includes any individual, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity; any State or political subdivision thereof; any municipality; any interstate body; and any department, agency, or instrumentality of the Federal Government.

Possession or control means in the possession or control of any person, or of any subsidiary, partnership in which the person is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the person in the research, development, test marketing, or commercial marketing of the substance in question. Information is in the possession or control of a person if it is:

(1) In the person's own files including files maintained by employees of the person in the course of their employment.

(2) In commercially available data bases to which the person has purchased access.

(3) Maintained in the files in the course of employment by other agents of the person who are associated with

research, development, test marketing, or commercial marketing of the chemical substance in question.

Process means to process for commercial purposes.

Process for commercial purposes means the preparation of a chemical substance or mixture after its manufacture for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included in this definition. If a chemical substance or mixture containing impurities is processed for commercial purposes, then the impurities also are processed for commercial purposes.

Processor means any person who processes a chemical substance or mixture.

Production volume means the quantity of a substance which is produced by a manufacturer, as measured in kilograms or pounds.

Propose to manufacture, import, or process means that a person has made a firm management decision to commit financial resources for the manufacture, import, or processing of a specified chemical substance or mixture.

Site means a contiguous property unit. Property divided only by a public right-of-way shall be considered one site. There may be more than one plant on a single site. The site for a person who imports a substance is the site of the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction and may in some cases be the organization's headquarters office in the United States.

Small manufacturer or importer means a manufacturer or importer that meets either of the following standards:

(1) *First standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$40 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 pounds), the manufacturer or importer shall not qualify as small for purposes

of reporting on the production or importation of that substance at that site, unless the manufacturer or importer qualifies as small under standard (2) of this definition.

(2) *Second standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$4 million, regardless of the quantity of substances produced or imported by that manufacturer or importer.

(3) *Inflation index.* EPA shall make use of the Producer Price Index for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics, for purposes of determining the need to adjust the total annual sales values and for determining new sales values when adjustments are made. EPA may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the Producer Price Index for Chemicals and Allied Products has changed more than 20 percent since either the most recent previous change in sales values or the date of promulgation of this rule, whichever is later. EPA shall provide FEDERAL REGISTER notification when changing the total annual sales values.

Small quantities solely for research and development (or "small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product") means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes.

Substance means either a chemical substance or mixture unless otherwise indicated.

Test marketing means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, article containing that chemical substance or mixture, or a mixture containing that substance, by a manufacturer or processor, to no

Environmental Protection Agency

§ 704.7

more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

Total annual sales means the total annual revenue (in dollars) generated by the sale of all products of a company. Total annual sales must include the total annual sales revenue of all sites owned or controlled by that company and the total annual sales revenue of that company's subsidiaries and foreign or domestic parent company, if any.

TSCA means the Toxic Substances Control Act, 15 U.S.C. 2601 et seq.

[53 FR 51715, Dec. 22, 1988]

§ 704.5 Exemptions.

A person who is subject to reporting requirements for a substance identified in this part is exempt from those requirements to the extent that the person and that person's use of the substance is described in this section. This section is superseded by any TSCA section 8(a) rule that adds to, removes, or revises the exemptions described in this section.

(a) *Articles*. A person who imports, processes, or proposes to import or process a substance identified in this part solely as part of an article is exempt from the reporting requirements of this part with regard to that substance.

(b) *Byproducts*. A person who manufactures, imports, or proposes to manufacture or import a substance identified in this part solely as a byproduct is exempt from the reporting requirements of this part.

(c) *Impurities*. A person who manufactures, imports, processes, or proposes to manufacture, import, or process a substance identified in this part solely as an impurity is exempt from the reporting requirements of this part.

(d) *Non-isolated intermediate*. A person who manufactures or proposes to manufacture a substance identified in this part solely as a non-isolated intermediate is exempt from the reporting requirements of this part.

(e) *Research and development*. A person who manufactures, imports, proc-

esses, or proposes to manufacture, import, or process a substance identified in this part only in small quantities solely for research and development is exempt from the reporting requirements of this part.

(f) *Small manufacturers and importers*. Small manufacturers and importers are exempt from the reporting requirements of this part.

[53 FR 51717, Dec. 22, 1988]

§ 704.7 Confidential business information claims.

(a) Any person submitting a notice under this rule may assert a business confidentiality claim covering all or any part of the notice. Any information covered by a claim will be disclosed by EPA only to the extent and by means of the procedures set forth in part 2 of this title.

(b) If no claim accompanies the notice at the time it is submitted to EPA, the notice will be placed in an open file available to the public without further notice to the respondent.

(c) To assert a claim of confidentiality for data contained in a notice, the respondent must submit two copies of the notice.

(1) One copy of the notice must be complete. In that copy the respondent must indicate what data, if any, are claimed as confidential by marking the specific information on each page with a label such as "confidential", "proprietary", or "trade secret".

(2) If some data in the notice are claimed as confidential, the respondent must submit a second copy. The second copy must be complete except that all information claimed as confidential in the first copy must be deleted.

(3) The first copy of the notice will be for internal use by EPA. The second copy will be placed in an open file to be available to the public.

(4) Failure to furnish a second copy of the notice when information is claimed as confidential in the first copy will be considered a presumptive waiver of the claim of confidentiality. EPA will notify the respondent by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The respondent has 15 days from the date of receipt of